

**UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF TEXAS  
MCALLEN DIVISION**

BETTY CAMPBELL and  
EDWARD CAMPBELL,

Plaintiffs,

VS.

AMERICAN MEDICAL SYSTEMS, INC.  
and ENDO PHARMACUETICALS  
HOLDINGS, INC.,

Defendant(s).

Civil Action No.

## COMPLAINT AND JURY DEMAND

### COMPLAINT AND DEMAND FOR JURY TRIAL

COME NOW the Plaintiffs, BETTY CAMPBELL and EDWARD CAMPBELL and file this Original Complaint against the Defendants American Medical Systems, Inc. and Endo Pharmaceuticals Holdings, Inc. (hereinafter jointly referred to as AMS) as follows:

### NATURE OF CASE

1. This is an action for damages suffered by BETTY CAMPBELL (“Plaintiff”), as a direct and proximate result of AMS’ wrongful conduct in connection with the development, design, manufacture, marketing, distribution and selling of AMS’ Pelvic Mesh Products<sup>1</sup> inserted in her body to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. This is also an action for damages suffered by the plaintiff EDWARD CAMPBELL, the spouse of Plaintiff, for claims and damages arising from the AMS’ Pelvic Mesh Products.

<sup>1</sup> The term Pelvic Mesh Products includes AMS’ mesh, hammock and sling products used to treat pelvic organ prolapse and/or stress urinary incontinence. The term Pelvic Mesh Products also specifically includes the AMS products implanted into Plaintiff, which include the AMS Monarc (hereinafter “Products”).

### **PARTIES**

2. Plaintiffs BETTY CAMPBELL and EDWARD CAMPBELL are citizens of the State of Alabama, County of Houston, and City of Dothan.

3. Defendant American Medical Systems, Inc. is a for profit corporation organized and existing under the laws of Delaware with its corporate headquarters in Minnesota. American Medical Systems, Inc. may be served through its registered agent at American Medical Systems, Inc., 3070 Orchard Drive, San Jose, California 95134; its president Anthony P. Bihl, III at 10700 Bren Road West, Minnetonka, Minnesota 55343; or the Delaware Registered Agent for Service, Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

4. Defendant Endo Pharmaceuticals Holdings, Inc. is a for profit corporation organized and existing under the laws of Delaware with its corporate headquarters in Pennsylvania. On June 20, 2011, AMS became a wholly owned subsidiary of Endo Pharmaceuticals Holdings, Inc. Endo Pharmaceuticals Holdings, Inc. may be served through its registered agent at Endo Pharmaceuticals Holdings, Inc. 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317; or the Delaware Registered Agent for Service, Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

### **JURISDICTION AND VENUE**

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants American Medical Systems, Inc. and Endo Pharmaceuticals Holdings, Inc. are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

6. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiffs' claims occurred in this district. At all times material hereto, AMS was a for profit corporation authorized to and doing substantial business in this district.

7. At all times material hereto, AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products at issue in this matter. By said activities, AMS' Pelvic Mesh Products, including but not limited to the Monarc, are placed into the stream of commerce throughout the United States, including within the State of Texas.

8. AMS is subject to personal jurisdiction in the U.S. District Court for the Southern District of Texas as AMS systematically and continually conducts business in this District and conducts business throughout the United States.

**FACTUAL ALLEGATIONS**  
**AMS PELVIC ORGAN PROLAPSE PRODUCTS BACKGROUND**

9. AMS develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution Pelvic Mesh Product medical devices for the treatment of medical conditions in the female pelvic, primarily pelvic organ prolapse and stress urinary incontinence.

10. AMS' Pelvic Mesh Products were derived from AMS' polypropylene mesh hernia products, and were and are utilized in the treatment of medical conditions in the female pelvic, primarily pelvic organ prolapse and stress urinary incontinence.

11. AMS develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the

sale and distribution medical devices, including medical devices implanted to treat certain women, like Plaintiff, for pelvic organ prolapse and stress urinary incontinence such as the AMS Monarc (hereinafter “Products”). The Pelvic Mesh Products known as Monarc as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as AMS’ Pelvic Mesh Products or the Pelvic Mesh Products.

12. Plaintiff BETTY CAMPBELL was implanted with AMS Pelvic Mesh Products developed, designed, manufactured, marketed, packaged, labeled, distributed, supplied, advertised, sold and placed in the stream of commerce by AMS. Due to defective design, defective manufacturing, defective marketing, failure to warn and negligence by AMS, the Products have caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering, as well as economic losses.

13. AMS’ Pelvic Mesh Products, including the Pelvic Mesh Products specifically used for Plaintiff, have been and continue to be marketed to the medical community and to patients as safe, effective, reliable medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. AMS markets the Pelvic Mesh Products, including the Products specifically used for Plaintiff, as safer and more effective when compared to 1) the traditional products and procedures for treatment of pelvic organ prolapse and stress urinary incontinence and 2) other competing pelvic mesh and sling products.

14. AMS made public statements in the form of written product descriptions, product labels, promotional materials, marketing materials and other materials that asserted that implanting the Pelvic Mesh Products in patients was safe and would not cause harm to patients,

like Plaintiff. AMS has also marketed and sold its Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, telephone information lines, and training offering exaggerated and misleading expectations as to the safety and utility of the AMS' Pelvic Mesh Products.

15. Contrary to AMS' representations and marketing to the medical community and to the patients themselves, AMS' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to the Plaintiffs. These defects include, but are not limited to:

- a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.
- b. The mesh material harbors infections that adversely affect human tissues and patient health.
- c. The Pelvic Mesh Products migrate from the location of their implantation, adversely affecting tissues and patient health.
- d. The mesh material abrades tissues adversely affecting patient health.
- e. The Pelvic Mesh Products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

- f. Due to their various defects, the Pelvic Mesh Products regularly cause significant injury to patients such that the Pelvic Mesh Products must be removed, resulting in additional surgery.
- g. The Pelvic Mesh Products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.
- h. The Pelvic Mesh Products are defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.
- i. The Pelvic Mesh Products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.

16. Because of their numerous defects, the Pelvic Mesh Products create an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to the woman's intimate partner.

17. AMS made, participated in and/or contributed to filings with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for AMS' Pelvic Mesh Products.

18. Upon information and belief, AMS sent to the FDA a 510(k) submission for its Pelvic Mesh Products.

19. Upon information and belief, AMS was in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of product warnings and related information with respect to its Pelvic Mesh Products.

20. AMS has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

21. AMS has known and continues to know that its disclosures to the FDA were and are incomplete and misleading; and that its Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. AMS suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, AMS actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that its Pelvic Mesh Products were and are safe, effective, and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public

would pay for the Pelvic Mesh Products and that the Pelvic Mesh Products would be implanted in patients. When AMS made these statements, AMS knew or should have known that the statements were inaccurate.

22. AMS has at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the AMS' Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

23. AMS was at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the clearance process, labeling and other marketing activities that pertain to the its Pelvic Mesh Products.

24. AMS failed to perform or rely on proper and adequate testing and research in order to determine the safety and effectiveness of its Pelvic Mesh Products.

25. AMS failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the its Pelvic Mesh Products.

26. AMS failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products; therefore, in the event of a failure, injury, or complication it is impossible to easily and safely remove AMS' Pelvic Mesh Products.

27. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the AMS' Pelvic Mesh Products.

28. AMS' Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to AMS.

29. The Pelvic Mesh Products implanted into the Plaintiff were in the same or substantially similar condition as they were when they left the possession of AMS, and in the condition directed by AMS.

30. The injuries, conditions and complications suffered due to AMS' Pelvic Mesh Products include but are not limited to mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to the woman's intimate partner.

31. Despite AMS' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, AMS has, and continues to manufacture, market and sell the Pelvic Mesh Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to AMS' Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

32. Prior to the time that the Pelvic Mesh Products were implanted into Plaintiff, AMS was aware of numerous defects in the Pelvic Mesh Products, including, but not limited to, the defects and unreasonable risks identified above. Based thereon, AMS knew or should have

known that the Pelvic Mesh Products caused an unreasonably high rate of complications, such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs in women implanted with the Pelvic Mesh Products. Despite being aware of the numerous defects and unreasonable risks in its products, AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products with the intent that it would be implanted in patients. AMS was aware that implanting the Pelvic Mesh Products in patients was likely to cause injury and harm to the patients into whom the Pelvic Mesh Products were implanted. Alternatively, AMS failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

33. Even though AMS has known or should have known that the Pelvic Mesh Products created a foreseeable, unreasonable risk of harm to those women into whom they were implanted, AMS continued to market the Pelvic Mesh Products in the United States. AMS has sold thousands of Pelvic Mesh Products in the United States alone.

34. AMS has failed to provide adequate warning or information about the risks that the Pelvic Mesh Products cause an unreasonably high rate of complications, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs to

physicians who implanted the Pelvic Mesh Products, or to women implanted with the Pelvic Mesh Products.

**CASE SPECIFIC ALLEGATIONS**

35. On or about January 26, 2006, at Rio Grande Regional Hospital in McAllen Texas, Plaintiff's physician implanted AMS Pelvic Mesh Products, that being the AMS Monarc to treat pelvic organ prolapse and/or stress urinary incontinence.

36. Prior to Plaintiff's surgery, her treating physician, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directed by AMS.

37. Plaintiff and her physician, either through direct promotional contact with AMS Sales Representatives, Lab Faculty, through word-of-mouth with other health care providers, and/or through promotional materials, received the information AMS intended Plaintiff and her physician to receive and view, to wit: that the Pelvic Mesh Products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

38. Plaintiff began experiencing severe and debilitating pain, infections, vaginal scarring/shrinkage, and mesh erosion some time after implant.

39. Plaintiff returned to her physicians several times due to complications and problems attributed to AMS' Pelvic Mesh Products.

40. As a direct and proximate result of the use of the AMS Pelvic Mesh Products, Plaintiff suffered, and continues to suffer, serious bodily injury and harm including removal of the AMS Pelvic Mesh Products on or about June 13, 2012. The removal of AMS' Pelvic Mesh Products resulted in a hospitalization as well as related complications.

41. As a direct and proximate result of the use of the AMS Pelvic Mesh Products, that being the Monarc, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

**COUNT I**  
**STRICT LIABILITY – DEFECTIVE MANUFACTURE**

42. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

43. One or more of the defects in the Pelvic Mesh Products are the result of improper or incorrect manufacturing processes that result in the Pelvic Mesh Products as manufactured deviating from its intended design. The defects caused by improper or incorrect manufacturing rendered the Pelvic Mesh Products unreasonably dangerous to consumers and to Plaintiff. The defects in the Pelvic Mesh Products implanted in Plaintiff existed from their manufacture; therefore the defects were present when they left the possession and control of AMS. The Pelvic Mesh Products were used by Plaintiff in a reasonably foreseeable and intended manner.

44. AMS' Pelvic Mesh Products were "defective" and "unreasonably dangerous" when they entered the stream of commerce and were received by Plaintiff. The Pelvic Mesh Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

45. The Pelvic Mesh Products used by Plaintiff's physician were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Pelvic Mesh Products reached the Plaintiff in such a condition that was unreasonably dangerous to her. The AMS Pelvic Mesh Products were used in the manner for which it was intended, that

is, for treatment of pelvic organ prolapse and/or stress urinary incontinence. This use resulted in injury to Plaintiff.

46. At no time did Plaintiff have reason to believe that Pelvic Mesh Products were in a condition not suitable for its proper and intended use among patients.

47. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Pelvic Mesh Products. Further, in no way could Plaintiff have known that AMS had manufactured the Pelvic Mesh Products in such a way as to increase the risk of harm or injury to the recipients of the implant.

48. AMS violated the common law as well as Texas Civil Practice & Remedies Code § 82.001, *et. seq.*

49. As a direct and proximate result of AMS' wrongful conduct, including AMS' defective manufacturing, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

**COUNT II**  
**STRICT LIABILITY – DESIGN DEFECT**

50. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

51. AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution the Pelvic Mesh Products, which are defective and unreasonably dangerous to consumers.

52. The Pelvic Mesh Products are defective in their design or formulation as they have numerous defects that adversely affect patient health. The defects in the Pelvic Mesh Products existed from their inception. The Pelvic Mesh Products are not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceeded the benefits associated with its design and formulation. The Pelvic Mesh Products are defective in design or formulation in that they lack efficacy and/or they pose a greater likelihood of injury than other pelvic organ prolapse and stress incontinence surgeries and are more dangerous than ordinary consumers can reasonably foresee.

53. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the Pelvic Mesh Products did not outweigh the risk of marketing a product designed in that manner.

54. The defective condition of the Pelvic Mesh Products rendered it unreasonably dangerous and/or not reasonably safe, and the Pelvic Mesh Products were in this defective condition at the time it left the hands of AMS. The Pelvic Mesh Products were expected to and did reach consumers, including Plaintiff, without substantial change in the condition in which it was developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise released into the stream of commerce.

55. Plaintiff and her physician were unaware of the significant hazards and defects in the AMS Pelvic Mesh Products.

56. The Pelvic Mesh Products were unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used the Pelvic Mesh Products, it was being utilized in a manner that was intended by AMS.

57. At the time Plaintiff received and used the Pelvic Mesh Products, it was represented to be safe and free from latent defects.

58. AMS is strictly liable to Plaintiff for designing, manufacturing and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of AMS because of the design defects.

59. AMS knew or should have known of the danger associated with the use of the Pelvic Mesh Products, as well as the defective nature of the Pelvic Mesh Products, but continued to develop, design, manufacture, label, package, distribute, market, supply, advertise, sell and otherwise engage in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Pelvic Mesh Products.

60. AMS violated the common law as well as Texas Civil Practice & Remedies Code § 82.001, *et. seq.*

61. The foreseeable risks of harm posed by the design of the Pelvic Mesh Products could have been reduced and/or avoided by the adoption of a reasonable alternative design by AMS, and the failure of AMS to adopt a safer alternative design rendered the Pelvic Mesh Products unreasonably safe.

62. As a direct and proximate result of AMS' wrongful conduct, including AMS' defective design, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

**COUNT III**  
**FAILURE TO WARN – MARKETING DEFECT**

63. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

64. The Pelvic Mesh Products were defective by reason of failure of AMS to provide adequate warnings or instructions.

65. AMS failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, if any, and the safest and most effective methods of implantation and use of AMS' Pelvic Mesh Products.

66. AMS failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products.

67. AMS failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Pelvic Mesh Products or to those women who had been implanted with the Pelvic Mesh Products, concerning the following risks, given their condition and need for information. AMS had actual or constructive knowledge of the following risks at the time the Pelvic Mesh Products left AMS' control and was being marketed:

- a. The high failure rate of the Pelvic Mesh Products;
- b. The high rate of infections and abscesses caused by the Pelvic Mesh Products;
- c. The high rate of vaginal erosions and extrusions caused by the Pelvic Mesh Products;
- d. The high rate of chronic pain caused by the Pelvic Mesh Products;

- e. The necessity to remove the Pelvic Mesh Products from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion or other complication; and
- f. The difficulty in removing the Pelvic Mesh Product from the patient's body, including the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

68. After receiving notice of numerous bodily injuries resulting from the Pelvic Mesh Products, AMS failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the Pelvic Mesh Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore AMS failed to provide post-marketing or post-sale warnings to instructions concerning the necessity to remove the Pelvic Mesh Products from the patient's body in the event of the product failure or other complications.

69. AMS intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the AMS Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

70. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

71. AMS is strictly liable in tort for their wrongful conduct as it violated Texas Civil Practice & Remedies Code § 82.001, *et. seq.* as well as the common law.

72. As a direct and proximate result of AMS' wrongful conduct, including AMS' inadequate warnings and instructs, both at the time of marketing and after the sale of the Pelvic Mesh Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

#### **COUNT IV** **NEGLIGENCE**

73. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

74. At all times relevant herein, AMS had a duty to exercise reasonable care in the development, design, manufacture, label, packaging, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products, including a duty to ensure that the Pelvic Mesh Products did not pose a significantly increased risk of bodily injury to its users.

75. AMS had a duty to exercise reasonable care in the advertising and sale of the Pelvic Mesh Products, including a duty to warn and instruct Plaintiff and other consumers, of the dangers associated with the use of the Pelvic Mesh Products that were known or should have been known to AMS at the time of the sale of the Pelvic Mesh Products to the Plaintiff.

76. AMS knew or should have known Plaintiff could foreseeably suffer injury as a result of AMS' failure to exercise ordinary care as described above.

77. AMS failed to warn the general public, including Plaintiff, of the risk of serious harm.

78. AMS breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

79. AMS failed to exercise ordinary and reasonable care in the development, design, manufacture, label, packaging, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products. AMS negligently failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Pelvic Mesh Products.

80. As a direct and proximate result of AMS' wrongful conduct, including AMS' defective manufacturing, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

**COUNT V**  
**BREACH OF WARRANTY**

81. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

82. AMS developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of their product, the Pelvic Mesh Products, representing the quality and effectiveness to health care professionals, the FDA, Plaintiff and the public in such a

way as to induce its purchase or use, thereby making an express and implied warranty that the AMS Pelvic Mesh Products would conform to the representations. More specifically, AMS represented that the Pelvic Mesh Products were safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's conditions.

83. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good and become part of the basis of the bargain creating an express warranty, and an implied warranty, that the good shall conform to the affirmations of fact or promises.

84. At all relevant times, Plaintiff used the AMS Pelvic Mesh Products for the purpose and in the manner intended by AMS.

85. The AMS Pelvic Mesh Products did not conform to the representations made by AMS in that the Pelvic Mesh Products were not safe and effective, were not safe and effective for use by individuals such as Plaintiff, and/or were not safe and effective to treat in individuals, such as Plaintiff. The Pelvic Mesh Products implanted in Plaintiff failed to function as intended and as represented by AMS because they did not relieve the symptoms or otherwise alleviate the medical problems that they were intended to cure. Instead, the Pelvic Mesh Products caused Plaintiff to suffer severe and debilitating pain, mesh erosion, exposure/extrusion/protrusion, infections, bleeding, dyspareunia, bladder problems and bowel problems and other severe adverse health consequences. Accordingly, the Pelvic Mesh Products were not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of AMS. Furthermore, AMS knew that the Pelvic Mesh Products were to be used for the particular purpose for which they were used on Plaintiff and knew that the expertise

of AMS was relied upon to furnish suitable goods. Because the Pelvic Mesh Products failed to conform to representations and were not suitable for the purpose for which they were used, AMS has breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose.

86. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

87. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

88. AMS violated the common law, Tex. Bus. & Com. Code Ann § 2.313, *et. seq.* as well as Tex. Bus. & Com. Code Ann § 2.314, *et seq.*

89. As a direct and proximate result of AMS' wrongful conduct, including AMS' breach of warranty, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

## **COUNT VI** **FRAUD**

90. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

91. AMS falsely and fraudulently have represented and continue to represent to the Plaintiff, medical and healthcare community, the FDA and the public that Pelvic Mesh Products had been tested and were found to be safe and effective.

92. The representations made by AMS were, in fact, false. When AMS made their representations, AMS knew and/or had reason to know that those representations were false, and

AMS willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

93. These representations were made by AMS with the intent of defrauding and deceiving the medical and healthcare community, Plaintiff and the public, and also inducing the medical and healthcare community, Plaintiff and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced a callous, reckless, willful and depraved indifference to the health, safety and welfare of Plaintiff.

94. In representations to Plaintiff and/or to Plaintiff's healthcare providers, AMS fraudulently concealed and intentionally omitted the following material information:

- a. That AMS' Pelvic Mesh Products were not as safe as other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;
- b. That the risk of adverse events with the AMS Pelvic Mesh Products was higher than with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;
- c. AMS' Pelvic Mesh Products were not adequately tested;
- d. That the limited clinical testing revealed that AMS' Pelvic Mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

- e. That AMS deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;
- f. That AMS was aware of dangers in the AMS Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;
- g. That AMS' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;
- h. That patients needed to be monitored more regularly than usual while using the AMS Pelvic Mesh Products and that in the event the Pelvic Mesh Product needed to be removed that the procedures to remove then had a very high failure rate and/or needed to be performed repeatedly;
- i. That the AMS Pelvic Mesh Products were manufactured negligently;
- j. That the AMS Pelvic Mesh Products were manufactured defectively;
- k. That the AMS Pelvic Mesh Products were designed negligently and designed defectively.

95. AMS was under a duty to disclose to Plaintiff and her physicians, the defective nature of the AMS Pelvic Mesh Products, including, but not limited to, the heightened risks of mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage,

pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs and other permanent injuries.

96. AMS had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used AMS' Pelvic Mesh Products.

97. AMS' concealment and omissions of material fact concerning the safety of the Pelvic Mesh products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the AMS Pelvic Mesh Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the AMS Pelvic Mesh Products.

98. At the time these representations were made by AMS, and at the time Plaintiff use AMS' Pelvic Mesh Products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

99. AMS knew and had reason to know that the AMS Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of AMS' Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

100. In reliance upon these false representations, Plaintiff was induced to, and did use AMS' Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. AMS knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind AMS' concealment and omissions, and that these included material omissions of facts surrounding the use of the AMS Pelvic Mesh Products, as described in detail herein.

101. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the AMS Pelvic Mesh Products.

102. Having knowledge based upon AMS' research and testing, or lack thereof, AMS blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public and Plaintiff's healthcare providers and physicians, that AMS' Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of AMS' research and testing, or lack thereof, AMS intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff and the public at large.

103. AMS had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers and physicians, and the United States Food and Drug Administration ("FDA").

104. The information distributed to the public, the medical and healthcare community, the FDA, and Plaintiff, by AMS included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the AMS Pelvic Mesh Products.

105. AMS intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the AMS Pelvic Mesh Products

specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the AMS Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or pelvic organ prolapse.

106. AMS intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

107. AMS chose to over-promote the purported safety, efficacy and benefits of the AMS Pelvic Mesh Products instead.

108. AMS' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical and healthcare community, and the Plaintiff; to gain the confidence of the public, the medical and healthcare community, and the Plaintiff; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce the public, the medical and healthcare community, and the Plaintiff to request, recommend, prescribe, dispense, purchase and continue to use AMS' Pelvic Mesh Products.

109. AMS made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that AMS' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

110. These representations, and others made by AMS, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

111. These representations, and others made by AMS, were made with the intention of deceiving and defrauding public, the medical and healthcare community, and the Plaintiff, and were made in order to induce Plaintiff, and her healthcare professionals, to rely on

misrepresentations, and caused Plaintiff to purchase, rely, use and request the AMS Pelvic Mesh Products and their healthcare professionals to dispense, recommend or prescribe the AMS Pelvic Mesh Products.

112. AMS recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the AMS Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products know to be dangerous and defective, and/or not as safe as other alternatives.

113. AMS willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff, as well as her healthcare professionals, into a false sense of security, so that Plaintiff and her healthcare provider would rely on AMS' representations, and Plaintiff would request and purchase the AMS Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe and recommend the AMS Pelvic Mesh Products.

114. AMS utilized direct-to-consumer advertising to market, promote and advertise the AMS Pelvic Mesh Products.

115. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the AMS Pelvic Mesh products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover AMS' false representations, nor would Plaintiff with reasonable diligence have discovered the true facts or AMS' misrepresentations.

116. Had Plaintiff know the true facts about the dangers and serious health and/or safety risks of the AMS Pelvic Mesh Products, Plaintiff would not have purchased, used or relied on AMS' Pelvic Mesh Products.

117. AMS' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

118. As a direct and proximate result of AMS' wrongful conduct, including AMS' fraud, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss in addition to loss of consortium.

**COUNT VII**  
**FRAUDULENT MISREPRESENTATION**

119. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

120. AMS is in a unique position of knowledge concerning the quality, safety and efficacy of AMS' Pelvic Mesh Products, which knowledge is not possessed by Plaintiff or their physicians, and AMS thereby holds a position of superiority over Plaintiffs and their physicians.

121. Despite their unique and superior knowledge regarding the defective nature of AMS' Pelvic Mesh Products, AMS continues to suppress, conceal, omit and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent to the intended use of AMS' Pelvic Mesh Products, as compared to other products and forms of treatment.

122. For example, scientists in the study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

123. AMS has concealed and suppressed material information, including limited clinical testing, that would reveal that AMS' Pelvic Mesh Products had a higher risk of adverse events, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, AMS has misrepresented the safety and efficacy of the Products.

124. AMS' representations about safety and efficacy are false, and AMS knew the representations were false when made, or in the alternative made such representations recklessly without any knowledge of the truth and as a positive assertion. AMS made such false representations about safety and efficacy through its written materials and speakers, including their advertisements, trainers, lab faculty, leave behinds, publications, regulatory submissions and other written and oral materials.

125. Upon information and belief, AMS' material misrepresentations were designed, and made with the intention, to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the AMS Pelvic Mesh Products. Plaintiffs and the medical community have relied upon AMS' material misrepresentations.

126. AMS took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and the medical providers and engaged in constructive fraud in their relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on AMS' misrepresentations.

127. As a direct and proximate result of AMS' wrongful conduct, including AMS' fraudulent misrepresentation, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss in addition to loss of consortium.

**COUNT VIII**  
**NEGLIGENT MISREPRESENTATION**

128. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

129. AMS, a for profit company, had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of urinary incontinence and pelvic organ prolapse. The representations made by AMS, in fact, were false.

130. AMS failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while AMS was involved in their development, design, manufacture, label, package, distribution, marketing, supply, advertisement, selling, quality control and otherwise engaged in all activities that are part and parcel of the sale and distribution in interstate commerce, because AMS negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

131. AMS breached their duty in representing that AMS' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians and the medical and healthcare community.

132. As a foreseeable, direct and proximate result of the negligent misrepresentation of AMS as set forth herein, AMS knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including mesh erosion,

extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, injuries to the woman's intimate partner and other severe and personal injuries, which are permanent and lasting in nature.

133. AMS took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and the medical providers and engaged in negligent misrepresentations in their relationship with Plaintiff and the medical providers. Plaintiff reasonably and justifiably relied on AMS' misrepresentations.

134. As a direct and proximate result of AMS' wrongful conduct, including AMS' negligent misrepresentation, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss in addition to loss of consortium.

**COUNT IX**  
**TEXAS DECEPTIVE TRADE PRACTICES ACT**

135. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

136. Plaintiff purchased and used AMS' Pelvic Mesh Products primarily for personal use and is a consumer as otherwise defined in Chapter 17 of the Texas Business & Commerce Code, Deceptive Trade Practices Act.

137. Had AMS not engaged in the deceptive conduct described herein, including misrepresentations in an effort to induce purchase, Plaintiff would not have purchased and/or paid for AMS' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

138. AMS engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Pelvic Mesh Products that would not have been paid had AMS not engaged in unfair and deceptive conduct.

139. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and misunderstanding.

140. Plaintiffs were injured by AMS' conduct. AMS' conduct was directed at patients, physicians and consumers to create demand for and sell AMS' Pelvic Mesh Products. Each aspect of AMS' wrongful and misleading conduct artificially created sales of AMS' Pelvic Mesh Products.

141. AMS had a statutory duty to refrain from unfair or deceptive acts or trade practices in the development, design, manufacture, label, package, distribution, marketing,

supply, advertisement, selling, quality control and otherwise engaged in all activities that are part and parcel of the sale and distribution of AMS' Pelvic Mesh Products.

142. Had AMS not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

143. AMS' deceptive, unconscionable, negligent, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*

144. AMS' actions, as complained of herein, constitute unfair competition or unfair, conscionable, deceptive, or fraudulent acts, or trade practices in violation of the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*

145. The Texas Deceptive Trade Practices Act is to protect consumers against unfair deceptive, fraudulent and unconscionable trade and business practices and false advertising. AMS is the developer, designer, manufacturer, labeler, packager, distributor, marketer, supplier, advertiser, seller, otherwise seller and distributor, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

146. AMS violated the Deceptive Trade Practices Act that was enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that AMS' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials. In addition, AMS engaged in other false, misleading

and/or deceptive acts or practices as listed in the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*

147. The actions and omissions of AMS alleged herein are uncured or incurable deceptive acts under the statutes enacted in Texas to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

148. AMS had actual knowledge of the defective and dangerous condition of the AMS' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

149. Plaintiff and the medical community detrimentally relied upon AMS' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

150. AMS' deceptive, unconscionable and fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

151. Pursuant to § 17.505, written notice is rendered impracticable by reason of the necessity of filing suit in order to prevent the expiration of the statute of limitations. Therefore, due to the anticipated defense arguments that the statute of limitations is based on the date of implant or that the Plaintiff should have discovered the occurrence of the false, misleading, or deceptive act or practice at least two years prior to the filing of this Complaint, notice under the Texas Deceptive Trade Practice Act is being served simultaneously with this Complaint.

152. By reason of the unlawful acts engaged in by AMS, and as a direct and proximate result thereof, Plaintiff has sustained and will continue to sustain ascertainable losses and

damages, including severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

153. As a direct and proximate result of AMS' violations of Texas' consumer protection laws, including as a result of the AMS' false, misleading and deceptive acts and/or practices, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount proven at trial.

**COUNT X**  
**LOSS OF CONSORTIUM**

154. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

155. Plaintiff EDWARD CAMPBELL is the spouse of Plaintiff, BETTY CAMPBELL, and as a direct and proximate result of AMS' conduct as described in this Complaint, Plaintiff EDWARD CAMPBELL has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

156. As a direct and proximate result of AMS' conduct as described in this Complaint, Plaintiff EDWARD CAMPBELL suffered and in the future will suffer the loss of his wife's affection, companionship, services, society and other damages.

157. As a direct and proximate result of AMS' conduct as described in this Complaint, Plaintiff EDWARD CAMPBELL is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past, present and future health and medical care costs related to the products, and any and all other damages allowed by law, in an amount to be determined at trial.

### **PUNITIVE DAMAGES**

158. Plaintiffs hereby incorporate by reference and reaver each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

159. At all times relevant hereto, AMS knew or should have known that the AMS Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

160. At all times material hereto, AMS attempted to misrepresent and did misrepresent facts concerning the safety of the AMS Pelvic Mesh Products.

161. At the time AMS designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Pelvic Mesh Products and failed to adequately warn Plaintiff of the dangerous and defective nature of the Pelvic Mesh Products and thereby caused Plaintiff's injuries, AMS knew, or in the exercise of the appropriate degree of care should have known, that its conduct created an extreme degree of risk of serious injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

162. AMS's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the AMS Pelvic Mesh Products.

163. At all times material hereto, Defendants knew and recklessly disregarded the fact that the AMS Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products and/or procedures and/or treatments.

164. At all times material hereto, AMS knew and recklessly disregarded the fact that the AMS Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

165. At all times material hereto, AMS intentionally misstated and misrepresented data and continued to misrepresent data so as to minimize the risk of injuries caused by the AMS Pelvic Mesh Products.

166. Notwithstanding the foregoing, AMS continues to aggressively market the AMS Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there are safer alternatives.

167. AMS knew of the AMS Pelvic Mesh Products' defective and unreasonably dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell the AMS Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the AMS Pelvic Mesh Products.

168. AMS continues to intentionally and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the AMS Pelvic Mesh Products in order to ensure continued and increased sales.

169. AMS's intentional, reckless, and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using the AMS Pelvic Mesh Products against their benefits.

170. As a direct and proximate result of AMS's wrongful conduct, including the acts and omissions listed above, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiffs pray for relief against Defendants American Medical Supply, Inc. and Endo Pharmaceuticals Holdings, Inc., jointly and severally, as follows:

- a) Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to totally compensate Plaintiffs for all of their injuries and damages, both past, present and future;
- b) Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, lost income, loss of earning capacity, permanent disability, and pain and suffering;
- c) Treble damages as allowed under the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*
- d) Punitive damages;
- e) Attorneys' fees, expenses, and costs of this suit;
- f) Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- g) Such other relief, monetary or equitable, as this Court deems necessary, just and proper

**JURY DEMAND**

Plaintiffs specifically demand a trial by jury of all claims asserted in this Complaint.

Dated: July 5, 2012

Respectfully submitted,

FLEMING, NOLEN & JEZ, LLP

/s/Karen Beyea-Schroeder

Karen Beyea-Schroeder

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